

REMARKS

Applicants respectfully request consideration and entry of the above amendment before examination, and before calculation of claim fees. Claims 1-61 have been canceled without prejudice, and new claims 62-81 have been added.

In addition, the specification has been amended without introducing any new matter, similar to amendments made in the parent application.

Respectfully submitted,

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VERSION WITH MARKINGS SHOWING CLAIM AMENDMENTS:

Page 1, first paragraph:

This application is a continuation of co-pending application Serial No. 09/634,689, filed August 8, 2000, which is a continuation of application Serial No. 08/942,938 filed on October 2, 1997, issued as U.S Patent No. 6,159,184, which is a continuation-in-part of application Serial No. 08/814,199, filed March 10, 1997, issued as U.S Patent No. 6,171,283.

Paragraph between page 3, line 3-14:

The present invention is directed to a guard or adapter for a medical cartridge, such as a unit dose cartridge or pre-filled syringe, that is used to inject medication or other drugs into a patient. Generally, the guard comprises two parts, namely a housing or body for receiving and holding the cartridge, and a protective case or shield slidably attached to the body. In addition, for a cartridge provided without its own plunger, an embodiment of the guard includes a finger grip plug that is attached to the body and a plunger connectable to the piston of the cartridge.

The various parts are generally molded from a suitable plastic, such as polypropylene, *synthetic resinous polymers of butadiene and styrene*, ~~resin~~ or polycarbonate, having a clear finish.

Paragraph between page 19, line 15 through page 20, line 4:

Turning to the drawings, FIG. 1 shows a first preferred embodiment of the present invention, namely a syringe guard 10 for holding a pre-filled unit dose syringe 90. Generally, the guard 10 comprises two parts, namely a housing or body 20 for receiving and holding the pre-

filled syringe 90, and a protective case or shield 60 slidably attached to the body 20. Both the body 20 and the shield 60 are generally molded from plastic, such as polypropylene, *synthetic resinous polymers of butadiene and styrene*, ~~resin~~ or polycarbonate, and are preferably clear and substantially colorless to facilitate observation of the pre-filled syringe received therein. Alternatively they may be translucent or opaque, and may be colored, such as a latex color, or a flesh tone, such as off-white, brown, or black.

Paragraph between page 34, lines 6-18:

As shown in FIG. 6A, because of the predetermined location of the distal detent pockets 42, when the stop tab 38 reaches the proximal edge 66 of the window 64, the detents 71 substantially simultaneously enter the distal detent pockets 42. The blunt or oblique proximal edges 71b of the detents engage the similarly shaped proximal edges 42b of the distal detent pockets 42, thereby preventing the shield 60 from being moved proximally. The corresponding shape of the engaged proximal edges 71b, 42b may also maximize bearing surface to prevent misalignment of the shield 60. Furthermore, because the stop tab 38 abuts the proximal edge 66 of the window 64, the shield 60 may not be moved further distally. Thus, the shield 60 is thereby substantially permanently locked in the guarded position.

Paragraph between page 35, lines 5-14:

Turning now to FIGS. 7-13, and 22-23, a second preferred embodiment is shown, namely a syringe guard 10 for holding a unit dose cartridge manufactured without its own plunger, such

as the unit dose glass cartridges /90 made by Carpuject and Tubex (see FIGS. 11A and 11B). Generally, the guard 10 comprises four parts, namely a housing or body 20 for receiving and holding the cartridge /90, a protective case or shield 60 slidably attached to the body 20, a finger grip plug 130, and a plunger 120. As before, the parts are molded from plastic, such as polypropylene, *synthetic resinous polymers of butadiene and styrene*, ~~k-resin~~ or polycarbonate, having a clear, colorless finish.

Paragraph between page 38, lines 1-13:

Referring now to FIGS. 10, 22, and 23, the plunger 122, preferably having a cruciform cross-section, has a thumb ring 128 on its proximal end 124 (FIG. 10), and a threaded bore 127 on its distal end 126. The threaded bore 127 is a shallow hole having a standard thread pattern, adapted to screw onto the threaded nipple 194 on the piston 193 on a conventional medical cartridge /90 (FIG. 23). Alternative distal ends 126 may be provided, such as a harpoon, a threaded nipple, an adhesive material, molded ribs, a frictional surface or the like (not shown), if appropriate for attaching to the piston of a desired medical cartridge. In addition, alternative proximal ends may be provided, such as a button end 248 (FIG. 22), or a "T" type thumb grip (not shown), instead of the thumb ring 128.

Paragraphs between page 40, line 10 and page 45, line 13:

The pre-assembled body 20 and shield 60 are then ready to receive a cartridge, such as the conventional unit dose glass cartridges /90a and /90b shown in FIGS. 11A and 11B

respectively, although alternatively, the device may be used to hold other vials, or ampules. The cartridges /90 generally comprise a barrel 92, a distal end or hub 94 including a hypodermic needle 95, a needle cover or cap (not shown), and a proximal end 93 having a threaded piston therein 193 (see FIG. 23).

Turning again to FIG 12, the distal end 94 of the cartridge /90 is inserted into the open proximal end 22 of the body 20. The cartridge /90 enters the cavity 26 and progresses distally until the distal end 94 of the cartridge /90 extends through or engages the distal end 24 of the body 20. Because different types of distal ends are provided on different cartridges, the distal point of engagement between the body 20 and the cartridge /90 may vary. For example, a standard Carpuject cartridge /90a, shown in FIG. 11A, requires the body 20 to have a distal end 24 similar to that shown in FIG. 8C, such that the distal ribs 94a on the cartridge /90a enter the opening 34 in the distal end 24 of the body 20. In contrast, a standard Tubex cartridge /90b, shown in FIG. 11B, requires a distal end 24 on the body 20 such as the collar 32 shown in FIG. 8B, thereby allowing the edge 94b on the cartridge /90b to engage the collar 32.

Turning to FIGS. 12 and 13, once the cartridge /90 is fully inserted into the cavity 26, the finger grip plug 130 is attached to the body 20. The fingers 138 on the finger grip plug 130 are aligned with the notches 116 in the finger grip collar 110 on the body 20. The fingers 138 are inserted into the notches 116, compressing the fingers radially as they enter the tapered pockets 118 (FIG. 8D) and pass through the collar 110. Upon reaching the windows 36, the fingers 138 expand radially outward again. The locking detents 139 have blunt proximal edges 139a which

engage the distal side 112b of the finger ring 112, thereby substantially permanently locking the finger grip plug 130 to the body 20.

Preferably, when the finger grip plug 130 is locked onto the body 20, the cartridge /90 is simultaneously encapsulated within the cavity 26 (FIG. 23). The body 20 generally has a length corresponding substantially to that of the cartridge /90. When the finger grip plug 130 is locked onto the body 20, the distal ends 139b of the fingers 138 then preferably engage the proximal end 93 of the cartridge /90, substantially preventing proximal movement of the cartridge /90.

In addition, the body 20 may be used to encapsulate a cartridge /90 that is substantially shorter than the length of the body 20 but has a similar diameter to that of the cavity 26. As shown in FIGS. 21A-21C, the distal end 24 may include one or more tabs 240 formed thereon for securing a cartridge, such as the standard Tubex cartridge /90b (see FIG. 11B), within the body 20. Preferably, a pair of semi-rigid tabs 240 are provided on the distal end 24 of the body 20 extending partially into the opening 34, each tab 240 having a generally ramped inner surface 240a and a substantially blunt distal surface 240b. The inner surface 240a preferably defines a diameter smaller than that of the hub 94 of the cartridge /90, while the diameter of the opening 34 is smaller than that of the barrel 92.

The tabs 240 are ramped distally inward, thereby allowing the hub 94 to be directed distally past the tabs 240, forcing the tabs 240 slightly outward. Once the hub 94 extends beyond the tabs 240, the tabs 240 resiliently snap back inward, the blunt distal edge 240b engaging the blunt proximal edge 94a of the hub 94. Thus, the opening 34 substantially prevents distal movement of the cartridge /90, while the tabs 240 prevent proximal movement.

Alternatively, the cavity 26 may include one or more tabs, annular ridges or similar retaining detents (not shown) at predetermined locations in the body 20 corresponding to the length of one or more short cartridges. When the cartridge 190 is directed into the body 20, the smooth-walled barrel 92 passes freely over the tab or ridge, preferably facilitated by a ramped proximal edge thereof. When the cartridge 190 is fully inserted into the body 20, the needle 95 should extend beyond the distal end 24 and the proximal end 93 should be engaged by a blunt distal edge of the tab or ridge, thereby preventing the cartridge 190 from withdrawing proximally into body 20 during use.

As shown in FIGS. 12, 13 and 23, with the cartridge 190 fully inserted into the body 20, the plunger 120 is then attached to the piston 193 in the cartridge 190, preferably by screwing the threaded bore 127 on the plunger 122 to a threaded nipple 194 on the piston 193. As described above, the plunger shaft 122 preferably includes a tab 220 for substantially permanently retaining the distal end 126 of the plunger 120 within the finger grip plug 130. The finger grip plug 130 includes a passage 140 extending distally therethrough for receiving the plunger 120. The passage 140 includes a lip 142, preferably extending radially about the passage 140, for engaging the tab 220 to substantially retain the plunger 120.

The tab 220 includes a ramped distal surface 220b which allows it to be forced inward when the distal end 126 of the plunger 120 is directed into the passage 140. Once the tab 220 passes distally beyond the lip 142, it resiliently returns to its outward extended position. If the plunger 120 is drawn proximally, the blunt proximal edge 220a abuts the lip 142, thereby preventing the plunger 120 from being pulled out of the finger grip plug 130. In addition, the

plunger shaft 122 may have a cross-section similar in size to the passage, preventing the fingers 138 from being forced radially inward and thereby further securing the finger grip plug 130 to the body 20 of the syringe guard 10.

Referring to FIG. 7, with the shield 60 in the unguarded position, the needle 95 of the cartridge 190 extends through the opening 65 and beyond the distal end 63 of the shield 60. The device is then ready to be used to deliver the medication contained within the cartridge 190.

Similar to the procedure described above, the user places his index and middle fingers on the finger ledges 132, and his thumb in the ring 128. The needle cover (not shown) is removed, the needle 95 is inserted into the patient, and the medication is dispensed by directing the plunger 122 distally with the thumb. As shown in FIG. 7, the windows 64 and 36 allow constant observation of the barrel 92 of the cartridge 190, allowing the user to closely monitor delivery of the medication.

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